



Medtronic

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 10-61
Rockville, MD 20852

Subjects: FDA's proposed strategy entitled "Reuse, Single Use Devices" released November 1, 1999, **docket number 99N-1491** and;

The draft guidance entitled "Processing and Reuse of Single-use Devices: Risk Categorization Scheme (Draft)" released for comment on December 9, 1999, **docket number 99N-1491**.

Dear Sir or Madam:

Medtronic, Inc. submits the attached comments on these related documents.

Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, specializing in implantable and interventional therapies that restore health, extend life and alleviate pain. Medtronic, Inc.'s operations are primarily focused on providing therapeutic, diagnostic and monitoring systems for cardiac rhythm management, cardiovascular, neurological, and spinal markets that in 1999 benefited over 1.5 million patients worldwide.

In general, Medtronic supports the regulation of third-party reprocessed single-use devices as new, multiple-use devices with due consideration being given to the risks that result from uncontrolled processes including devices use and recovery. There are important aspects of the proposals that are deficient in this regard. These deficiencies are explained in the attached comments.

Medtronic appreciates the opportunity to comment on these documents.

Sincerely,

Chip Whitacre
Director, Corporate Regulatory and
Clinical Affairs

00D-0053

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Medtronic comments on FDA's proposed strategy entitled "Reuse, Single Use Devices" released November 1, 1999 (docket number 99N-1491)

General

Medtronic is generally in support of those aspects of the proposed strategy that would regulate third-party reprocessors to the same extent as original equipment manufacturers, (OEM)s. Anything less is an abdication of FDA's responsibility under the law. Because it is being offered for sale as reusable, a reprocessed single-use device (SUD) is improperly labeled unless it meets the applicable regulations as an investigational device or a new device.

As a consequence of the reuse of SUDs, Medtronic is concerned the medical practitioners and patients are being treated to a double standard in the devices that are offered for sale for use in medical practice. At a minimum, patients on whom SUDs are reused should be asked to provide their informed consent.

The proposed strategy is deficient in not addressing the subject of proper labeling of a reprocessed SUD. Recommendations in this regard are added at the end of the comments.

Comments on selected parts of the strategy.

1. Reconsider the agency's current policy on establishments that reprocess SUDs.

Medtronic agrees that third-party reprocessors should be regulated in the same manner as OEMs. The third-party reprocessor is, in fact, a manufacturer of a multiple use device and should be held to all the regulations applicable to any manufacturer that offers a multiple use device for sale, whether fabricated from purchased parts and materials or processed from a used SUD.

2. Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risk.

(See comments provided under the same cover on "Reprocessing and Reuse of Single-use Devices: Risk Categorization Scheme (Draft)" that was released for comment on December 9, 1999.)

3. Solicit comments on the FDA's draft list of "Frequently Reprocessed SUDs".

Consistent with the general comment above, the FDA should apply the regulations to the manufacturers of the devices on the draft list who use used SUDs as source materials as they would to the manufacturer of a new multiple-use device.

4. Consider requesting OEMs to provide information on their labels about risks associated with reuse of SUDs.

The original manufacturer of a SUD should not be expected to provide information about reuse. The objective of single-use is to preclude the risks associated with multiple-use. These well-known risks are avoided easily by single-use. To discuss reuse in any way in the labeling of a SUD is to give tacit approval to reuse "under some circumstances". Reuse information in labeling is appropriate for a multiple-use device since this is consistent with the intended use of the device and the user needs such guidance to assure safe and effective reuse. Accordingly, the third-party reprocessor that manufactures a multiple-use device from a used SUD should provide any qualifications associated with the claim of multiple-usability.

Requiring OEMs to commit resources to provide information on the risks of reuse would provide benefit only to the reprocessor who is offering a product with more intrinsic risk to compete with that of the OEM.

5. Examine the need to create working definitions for the terms "single-use device", "reuse", "reprocessing", and "resterilization".

For equitable application of the law, it is essential the all third-party reprocessing of SUDs be considered "manufacturing". This should be true regardless of what type and how many specific processes are involved. With this concept firmly established, there is little need for additional definitions.

6. Explore how recognized consensus standards can be applied to reprocessing SUDs (e.g., to verify and validate cleaning, disinfection and/or sterilization of SUDs) and explore the development of additional consensus standards to address the safety, effectiveness, and performance of reprocessed SUDs.

While consensus product standards address aspects of safety and effectiveness, they are insufficient to ensure safety and effectiveness. Controlled processes are needed to ensure safety and effectiveness. There are certain processes associated with SUD reuse that are uncontrolled, including use and recovery of the SUD.

7. Consider developing a research program on reuse of SUDs and explore avenues to publish and disseminate research and other information on reuse.

A research program on the reuse of SUDs would have value only if applied to third-party reproducers that are regulated on a par with manufacturers of multiple-use devices. This would give some assurance that what was being studied is the result of defined and controlled processes. Extrapolations based on such research would be risky, however, because SUDs can be expected to be introduced as time goes on that are more safe and/or effective in the single-use mode that could well be less safe and/or effective as reprocessed.

In terms of priority, research on multiple-use devices would be necessary to establish a bench mark before studying reuse of comparable SUDs.

An additional important subject that warrants clarification is that of proper labeling of a reprocessed SUD.

Further clarification and enforcement of labeling requirements by reproprocessors of reprocessed and reused SUDs is essential. In addition to requiring reproprocessors of a SUD to include with the reprocessed device labeling equivalent to that provided by the OEM (including; product identification, indications for use, warnings, precautions, contraindications, and user instructions), the reproprocessor must be required to label the actual device itself as reprocessed. In order for the reproprocessor to be in compliance with identification and traceability requirements of the Quality System Regulations, the reproprocessors' lot control number must be clearly identified on the reprocessed device.

It is important that reproprocessor accept full product liability in the case of patient injury from reuse of a device that the OEM has designed and manufactured to be used only for single use. Without the reproprocessors' process/lot control identification on the reprocessed SUD, once the device has been separated from its packaging there is no way to identify that the SUD has been reprocessed. Due to the potential for increased liability on the health care provider and reproprocessor in cases of device failure that result in patient injury from a reprocessed SUD, the healthcare provider and/or reproprocessor would have no incentive, after an adverse event, for identifying the SUD as reprocessed. Without proper reprocessing identification, blame for the device failure could easily and unjustly be transferred to the OEM.

Placing a unique identifier on reprocessed SUDs is also important for tracking and investigation of complaints and Medical Device Reports. The OEM cannot be held responsible for tracking and investigating device failures resulting from the use of reprocessed SUDs that have been designed, manufactured, and labeled by the OEM for single use. Recognizing that a SUD may be reprocessed and reused more than once, these labeling considerations must be given full attention at each reprocessing. This will help to assure that the reproprocessor and health care provider that uses a reprocessed SUD are held fully responsible for it's use.

Medtronic comments on “Reprocessing and Reuse of Single-use Devices: Risk Categorization Scheme ” (docket number 99N-1491)

General comments

Medtronic supports regulation of third-party reprocessed SUDs that puts them on a par with new, multiple-use devices. Accordingly, the law must be applied fully regardless of the nature of the source of the material for the new, multiple-use device. In addition, enforcement priorities must be independent of the nature of the source material for the new, multiple-use device.

The Risk Categorization Scheme (RCS) as proposed implies full application of the law to third-party reprocessed SUDs. This should be made explicit. In the matter of enforcement priorities, however, the proposed RCS would provide for less effective regulation for some reprocessed SUDs with a high inherent risk than would be applied to the original SUD. The FDA's reasoning for this appears to proceed from (a.) the observation that the original SUD has already been subject to regulatory scrutiny and (b.) the assumption that the reprocessed SUD only needs a limited amount of additional scrutiny. This assumption fails to take into account the following:

- The OEM can no longer be responsible for the safety and efficacy of the SUD after the first use.
- The third-party reprocessor is now the responsible manufacturer.
- The third-party reprocessor is representing the reprocessed SUD to be a multiple-use device and is responsible for supporting this and other claims. These responsibilities include adequate instructions for use (including multiple use), indications/contraindications, warnings/precautions, problem reporting, QSR compliance, etc. as well as meeting premarket requirements as applicable.
- The third-party reprocessor is reprocessing used SUDs of several types harvested from a number of healthcare facilities that originated from a number of OEMs.

If applied, the RCS must deal with each model of device separately since the specific materials and design will bear on the risks of infection and performance changes due to use, recovery and reprocessing. The results of reprocessing one model should not be assumed to prove the ability to reprocess all models of a type. This concern can be addressed by making it incumbent on the reprocessor to apply the RCS to each model from each OEM and submit valid evidence supporting the category chosen along with the reprocessing methods and labeling for FDA review prior to marketing.

Specific Comments

General Approach

The phrase “reprocessing and/or reuse” is used here and elsewhere in the draft. This is not consistent with the overall title of the draft and suggests that reuse may go on without some form of reprocessing.

In the absence of more explanation as to the regulatory consequences of the risk categorization, it is easy to conclude that reprocessed SUDs will be subject to less regulatory attention than the original SUD. An outline of the regulations and enforcement approach proposed to apply to each risk category is needed.

How to Determine the Reuse and Reprocessing Risks of a SUD

Initial use and recovery may alter the characteristics of the SUD as well as reprocessing. Because of the circumstances, initial use and recovery are uncontrolled processes as compared to the processes used to manufacture the SUD. Experience with GMP and quality systems shows that controlled processes are needed to ensure safety and effectiveness. It is not sufficient to test/inspect the resulting product. To the extent processes are uncontrolled, safety and effectiveness cannot be ensured. To the extent that safety and effectiveness is not ensured, there is intrinsic, undeniable increase in risk.

For the reprocessed SUD, the dimensions of this increased risk include such subjects as infection and inadequate performance. The RCS, as presented, does not account for uncontrolled processes such as initial use and recovery as sources of risk. Because the risks that arise from uncontrolled processes are, by nature, unknown, the assumption must be that they are significant unless shown to be otherwise by conclusive evidence.

A possible approach to addressing this issue is to add an increment to the total in applying the RCS to a specific product. As the possible consequences of uncontrolled processes would arguably be greater for Class II and III SUDs, the increment added should be larger. A modified Work Sheet from the RCS is attached to illustrate how uncontrolled process risk could be included in scoring a reprocessed SUD.

If, in a premarket submission, a reprocessor can provide conclusive evidence that a particular device model is unaffected by the processes of initial use and recovery, a lower category could be designated.

Flow Chart 1 : Evaluating the Risk of Infection

Item 2. is an important observation that clearly indicates that devices must be evaluated on a model-by-model basis. This should be clearly stated along with the requirement that each model have a specific reprocessing procedure. If several models of an SUD are subjected to the same reprocessing procedure, the probability of bioburden remaining on some models after cleaning will be higher than on others.

As noted above, the existence of uncontrolled processes supports a prudent assumption of increased risk. Waiting until this is confirmed by postmarket information, as suggested in item 3. before action is taken, implies the acceptance of a lower standard for reprocessed SUDs.

The uncontrolled processes noted above may also damage or alter the antimicrobial materials, coating or components noted in item 4.

Flow chart 2 : Evaluating the Risk of Performance Change

Item 1. appropriately brings in the effect of SUD use and gives examples of performance degradation. Since use is an uncontrolled process from the vantage point of the SUD, it is important to acknowledge that latent defects may be a consequence.

Item 2. strongly implies that testing to a standard or other document will reliably eliminate devices with inadequate performance. As discussed above, process control is needed to assure safety and effectiveness. Testing the resulting product is insufficient. The risk of introducing latent defects due to uncontrolled processes is one example of why testing is insufficient.

Item 3. correctly cautions against using questionable criteria for testing but fails to acknowledge that testing of any kind is insufficient to assure safety and effectiveness.

Opened but Unused Devices

Further information should be developed of the incidence of such devices before regulatory action is proposed.

Applying the RCS: Examples

Regarding example 1: A general conclusion that a single use of all devices of this type would not affect performance is presumptive and fails to consider design and material differences between models as well as variations in handling, use and recovery in the health care setting.

Regarding example 2 : While the cardiac ablation catheter ends up as a high risk device in this example of applying the RCS, it is still not clear that the reprocessed device will be regulated as diligently as the OEM device. Model differences as well as the uncontrolled processes discussed earlier in these comment are also not considered in the example.

Work Sheet

(with suggested change to address uncontrolled processes)

Inherent Risk (According to 21 CFR Part 860)

Class I = 0

Class II = 1

Class III = 2

Risk of Infection

(See Flowchart 1)

Grade 0 = 0

Grade 1 = 1

Grade 2 = 2

Risk of Inadequate Performance

(see Flowchart 2)

Grade 0 = 0

Grade 1 = 1

Grade 2 = 2

Risk due to Uncontrolled Processes*

Class I = 1

Class II = 2

Class III = 3

If the SUD resulted in a score of 2 for questions 2 or 3 listed above, the SUD is categorized as high risk.

Otherwise, the score should be totaled.

Total

Low Risk: 0-2

Moderate Risk: 3-4

*** Initial use and recovery processes**

HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CROSS REFERENCE SHEET

Docket Number/Item Code: 99N-4491/C105

See Docket Number/Item Code: 00D-0053/C1

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